SUPPLEMENTARY APPENDIX

Supplement to: Tess Petersen, Kerry Townsend, et al. High Adherence to All Oral Directly
Acting Antiviral HCV Therapy Among Inner City Patient Population in Phase 2A Study

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Supplemental Table 1: Seven Points Covered At Initiation of Directly Acting

Antiviral Therapy for Hepatitis C

- Adherence measures were in order to correlate study outcomes with adherence after completion of study, and as such, would not affect participation/continuation in the study at any point
- Instruction regarding proper use of MEMS cap: Patients are to only open MEMS cap when ready to take dose and close MEMS cap following dose
- Patients instructed not to use a pill box for study drug
- Patient is to take her/his dose at exactly the same time each day
- Appropriate dosing of study drug reviewed with patients (1 tablet PO once daily (arm A), 2 tablets PO once daily (arm C), or 3 tablets PO once daily (arm B) with or without food
- Patients advised that it is OK to take dose (if forgotten), when she/he remembers within same day. Patients advised to not to double any doses (if dose forgotten until the next day)
- Patients reminded to bring Rx bottle to every visit

Adherence Baseline Questionnaire

| Dat | e: | | | <u>Self</u> | Interviewer | <u>Both</u> |
|--------------------|--|---------------------------------|-----------------------------------|--------------------------------|------------------------------------|----------------------------------|
| Pati | ient ID: | How A | Administered? | | | |
| Stu | dy Visit: | | | | | |
| sch line imp | e answers you give on this form will be used to edule. Please do the best you can to answer all through it. If you do not know how to answer a cortant study. STRUCTIONS: Please answer the following quest | the questions. question, ask | If you do not v your study nur | wish to answe se to help. T | er a question, p hank you for h | please draw a nelping in this |
| Α. | How sure are you that: | | | | | |
| | Please circle one response for each question. | Not at All Sure | Somewhat Sure | Very <u>Sure</u> | Extremely Sure | |
| 1. | You will be able to take all or most of the study medication as directed? | 0 | 1 | 2 | 3 | |
| 2. | The medication will have a positive effect on your health? | 0 | 1 | 2 | 3 | |
| В. | The following questions ask about your soci | al support. | | | | |
| | Please circle one response for each question. | Very <u>Dissatisfied</u> | Somewhat Dissatisfied | Somewhat Satisfied | Very <u>Satisfied</u> | |
| 1. | In general, how satisfied are you with the overall support you get from your friends and family members? | 0 | 1 | 2 | 3 | |
| | | Not At All | A Little Some | what A Lot | Not Applica | <u>ble</u> |
| 2. | To what extent do your friends or family members help you remember to take your medication? | 0 | 1 2 | 3 | 4 | |

C. People may miss taking their medications for various reasons. Here is a list of possible reasons why you may have missed taking any medications within the **past month**.

If you have **NOT** taken **any** medications within the **past month**, please

check this box and skip to Section f E. $f \Box$

In the past month, how often have you missed taking your medications because you:

Please circle one response for each question.

| | | Never | Rarely | <u>Sometimes</u> | Often | |
|-----|---|-------|--------|------------------|-------|--|
| 1. | Were away from home? | 0 | 1 | 2 | 3 | |
| 2. | Felt hassled or inconvenienced by medicine? | 0 | 1 | 2 | 3 | |
| 3. | Simply forgot? | 0 | 1 | 2 | 3 | |
| 4. | Had too many pills to take? | 0 | 1 | 2 | 3 | |
| | | | | | | |
| 5. | Felt worse when you took pills? | 0 | 1 | 2 | 3 | |
| 6. | Did not want others to notice you taking medication? | 0 | 1 | 2 | 3 | |
| 7. | Had a change in daily routine? | 0 | 1 | 2 | 3 | |
| 8. | Felt like the drug was toxic/harmful? | 0 | 1 | 2 | 3 | |
| | | | | | | |
| 9. | Fell asleep/slept through dose time? | 0 | 1 | 2 | 3 | |
| 10. | Felt sick or ill? | 0 | 1 | 2 | 3 | |
| 11. | Felt depressed/overwhelmed? | 0 | 1 | 2 | 3 | |
| 12. | Had problem taking pills at specified times (with meals, on empty stomach, etc.)? | 0 | 1 | 2 | 3 | |
| 13. | Ran out of pills? | 0 | 1 | 2 | 3 | |
| 14. | Felt like treatment was working? | 0 | 1 | 2 | 3 | |

| D W | hen was the | last time you | missed taking any of you | ur medications? | Check one h |
|-----|-------------|---------------|--------------------------|-----------------|-------------|
|-----|-------------|---------------|--------------------------|-----------------|-------------|

| Within the past week |
|------------------------|
| 1-2 weeks ago |
| 2-4 weeks ago |
| 1-3 months ago |
| More than 3 months ago |
| |

Never skip medications or not applicable

E. In the past week how often did you:

Please circle one response for each question.

| | | Never/ Rarely | Sometimes | Often | Mostly or <u>Always</u> |
|----|--|------------------|-----------|-------|----------------------------|
| 1. | Feel like you couldn't shake off the blues even with help from your family or friends? | 0 | 1 | 2 | 3 |
| 2. | Have trouble keeping your mind on what you were doing? | 0 | 1 | 2 | 3 |
| 3. | Feel that everything you did was an effort? | 0 | 1 | 2 | 3 |
| 4. | Have trouble sleeping? | 0 | 1 | 2 | 3 |
| 5. | Feel lonely? | 0 | 1 | 2 | 3 |
| 6. | Feel sad? | 0 | 1 | 2 | 3 |
| 7. | Feel like you just couldn't "get going"? | 0 | 1 | 2 | 3 |

F. In the past month, how often have you:

Please circle one response for each question.

| | | Never | Almost Never | Sometimes | Fairly Often | Very Often |
|-----|---|-------|-----------------|-----------|-----------------|---------------|
| 1. | Been upset because of something that happened unexpectedly? | 0 | 1 | 2 | 3 | 4 |
| 2. | Felt unable to control the important things in in your life? | 0 | 1 | 2 | 3 | 4 |
| 3. | Felt nervous and 'stressed'? | 0 | 1 | 2 | 3 | 4 |
| 4. | Felt confident in your ability to handle your personal problems? | 0 | 1 | 2 | 3 | 4 |
| 5. | Felt that things were going your way? | 0 | 1 | 2 | 3 | 4 |
| 6. | Found that you could not cope with all the things that you had to do? | 0 | 1 | 2 | 3 | 4 |
| 7. | Been able to control irritations in your life? | 0 | 1 | 2 | 3 | 4 |
| 8. | Felt that you were on top of things? | 0 | 1 | 2 | 3 | 4 |
| 9. | Been angered because of things that happened that were outside of your control? | 0 | 1 | 2 | 3 | 4 |
| 10. | Felt problems were piling up so high that you could not overcome them? | 0 | 1 | 2 | 3 | 4 |

G. People have various health habits. The following questions ask about your alcohol and drug use, past and current. 1. How often have you had a drink containing alcohol - a glass of beer, wine, a mixed drink, or any kind of alcoholic beverage - in the last 30 days? Check one. 3 or 4 Once or 2 or 3 Nearly Times Twice Times A Once **Every Day** A Week A Week Month A Month Never Daily If Never, skip ahead to question #4. On days when you drank any alcoholic beverages in the last 30 days, how many drinks did you usually have altogether? By a drink we mean a can or glass of beer, a 4-ounce glass of wine, a 1-1/2 ounce shot of liquor, or a mixed drink with 1-1/2 ounces of liquor? Check one. 1 or 2 3 or 4 9 - 11 5 or 6 7 or 8 12 or more Drinks Drinks Drinks Drinks Drinks Drinks Per Day Per Day Per Day Per Day Per Day Per Day During the past 30 days, how often have you had 5 or more drinks of alcohol in a row, that is, within a couple of hours (e.g. 2-4 hours)? Check one. 3 or 4 Once or 2 or 3 Times A Nearly Times Twice Once A Week A Week Month A Month Daily **Every Day** Never

| 4. | Please | chec | k "Yes" (| or "No" for eacl | າ question. |
|----|--------|------|-----------|------------------|--|
| | а | . 🗖 | Yes [| □No | Have you ever used marijuana? If you used this drug, have you used it within the past 6 months? |
| | | | | | ☐ Yes ☐ No |
| | b | . 🗖 | Yes | □ No | Have you ever used cocaine (powder, crack, or freebase)? If you used this drug, have you used it within the past 6 months? |
| | | | | | □ Yes □ No |
| | C. | | Yes | □ No | Have you ever used heroin? If you used this drug, have you used it within the past 6 months? |
| | | | | | □ Yes □ No |
| | d. | | Yes | □ No | Have you ever used amphetamines (speed)? If you used this drug, have you used it within the past 6 months? |
| | | | | | □ Ves □ No |

H. These last questions ask about your background.

| 1. | What | is the hig | hest le | vel of education you | have c | ompleted | d? (che | eck one) |
|----|------------------|-------------|-----------|-------------------------|-----------|-------------|---------|--|
| | | 11th grad | de or les | SS | | | | |
| | | High sch | ool grad | duate or GED | | | | |
| | | 2 years o | of colleg | je / AA degree / Techr | nical sch | ool trainir | ng | |
| | | College | graduat | e (BA or BS) | | | | |
| | | Master's | Degree | · • | | | | |
| | | Doctorate | e / med | ical degree / law degre | ee | | | |
| | | | | | | | | |
| 2. | What is question | | nost lik | ely way(s) that you b | ecame | infected | with I | nepatitis C? (check "Yes" or "No" for each |
| | a. Share | d needles | with a p | erson who was Hepa | titis C+ | | | |
| | □Ye | s | | No | | | | |
| | | | | | | | | |
| | b. Share | d straws (s | snorting |) with a person who w | as Hepa | atitis C+ | | |
| | □Ye | S | | No | | | | |
| | | | | | | | | |
| | | | | er medical procedure | | | | |
| | ■Ye | S | | No | | | | |
| | d Seyw | ith a nerso | n who v | vas Hepatitis C+ | | | | |
| | u. Sex w | | | No No | | | | |
| | | 3 | | 140 | | | | |
| | e. Don't | know | | | | | | |
| | □ Ye: | | | No | | | | |
| | | | | | | | | |
| | f. Other (| needle stic | k at wo | rk, etc.) | | | | |
| | □Ye | s | | No | | | | |
| | Di | | | | | | | |
| | Please s | ресіту: | | | | | | |
| | | | | | | | | |
| 3. | Do you | work for p | ay outs | side the home? | | Yes | | No |
| 4. | Do vou l | nave any c | hildre | 1? | | Yes | | No |
| | - | how many | | | _ | - | _ | |
| | 11 <u>1 65</u> , | HOW HIALLY | , iive w | itii you: | | | | |

Adherence Questionnaire: GS-7977/5885 Arm

Adherence Questionnaire: GS-7977/5885 FDC Arm

| D | ate | | | | Self | Interviewer | Both |
|--------------------------|--|--|--|--|---------------------|------------------------------|---------------------------------|
| St | tudy ID | | How Admin | istered? | | | |
| St | tudy Visit | | Trow / Grillin | iotorou : | _ | _ | _ |
| NS | STRUCTIONS: | | | | | | |
| sch so a li /Ol | nedule. Please do you don't worry about telli ne through it. If you do u for helping in this im | n this form will be used if best to answer all of ing us that you don't to not know how to ansportant study. | the questions hones ake your pills. If you do swer a question, ask | itly. We ne do not wish a member | ed to kn to ansv | ow what is reaver a question | ally happening , please draw |
| | | | HOW MANY DOSES | S DID YOU | MISS . | | |
| | Step 1 | Step 2 | Step 3 | Ste | р 4 | Step | 5 |
| | Hepatitis C study drug: | Yesterday | Day before yesterday (2 days ago) | 3 day | s ago | 4 days | s ago |
| | GS-7977/5885: 1 pill 1 dose per day | , | () () | | | | |
| | | at they forget to take ons last weekend- I | | | ays. Did | d you miss aı | ny of your |
| 3. | When was the last t | time you missed any | of your medication | ns? Check | one. | | |
| | | Within the past week | | | | | |
| | | 1-2 weeks ago | | | | | |
| | | 2-4 weeks ago | | | | | |
| | | 1-3 months ago | | | | | |
| | | Never skip medication | ns or not applicable | | | | |

4. People may miss taking their medications for various reasons. Here is a list of possible reasons why you may miss taking your medications. How often have you missed taking your medications because you: (Circle one response for each question.)

| | Never | Rarely | Sometimes | Often |
|--|-------|--------|-----------|-------|
| 1. Were away from home? | 0 | 1 | 2 | 3 |
| Felt hassled or inconvenienced by medicine? | 0 | 1 | 2 | 3 |
| 3. Simply forgot? | 0 | 1 | 2 | 3 |
| 4. Had too many pills to take? | 0 | 1 | 2 | 3 |
| 5. Felt worse when you took pills? | 0 | 1 | 2 | 3 |
| 6. Did not want others to notice you taking medication? | 0 | 1 | 2 | 3 |
| 7. Had a change in daily routine? | 0 | 1 | 2 | 3 |
| Felt like the drug was toxic/harmful? | 0 | 1 | 2 | 3 |
| Fell asleep/slept through dose time? | 0 | 1 | 2 | 3 |
| 10. Felt sick or ill? | 0 | 1 | 2 | 3 |
| 11. Felt depressed/overwhelmed? | 0 | 1 | 2 | 3 |
| 12. Had problems taking pills at specified times (with meals, on empty stomach, etc.)? | 0 | 1 | 2 | 3 |
| 13. Ran out of pills? | 0 | 1 | 2 | 3 |
| 14. Felt like treatment was working? | 0 | 1 | 2 | 3 |

SYNERGY ADHERENCE QUESTIONNAIRE: GROUP C

| Date | | | Study ID | | | Study Visit | | |
|---------------|-------------|---------------|--------------|---|-----------------|---------------|-----------------|--|
| • | | | · | ue pill) have you issed since you | | - | ıdy visit? | |
| 3. Since your | last stu | udy visit, ho | ow often did | you take your s | tudy medication | ons with food | ? Check one. | |
| | | All of the ti | me | | | | | |
| | | Most of the | e time | | | | | |
| | | About half | of the time | | | | | |
| | | Some of the | ne time | | | | | |
| | | Never | | | | | | |
| | | | | their pills on the ast Saturday or S | | /s. Did you m | iss any of your | |
| | ☐ Ye | S | □ No | | | | | |
| 5. When was | the las | t time you | missed any | of your study me | edications? Cl | neck one. | | |
| | | Within the | past week | | | | | |
| | | 1-2 weeks | ago | | | | | |
| | | 2-4 weeks | ago | | | | | |
| | | 1-3 month | s ago | | | | | |
| | | Never skip | medications | or not applicable | | | | |
| | | | | | | | | |

6. People may miss taking their medications for various reasons. Here is a list of possible reasons why you may miss taking your medications. Have you ever missed taking your study medications because you: (Circle one response for each question.)

| | | Never | Rarely | Sometimes | Often |
|----|---|-------|--------|-----------|-------|
| 1. | Were away from home? | 0 | 1 | 2 | 3 |
| 2. | Felt hassled or inconvenienced by medicine? | 0 | 1 | 2 | 3 |
| 3. | Simply forgot? | 0 | 1 | 2 | 3 |
| 4. | Had too many pills to take? | 0 | 1 | 2 | 3 |
| 5. | Felt worse when you took pills? | 0 | 1 | 2 | 3 |

SYNERGY ADHERENCE QUESTIONNAIRE: GROUP C

| 6. | medication? | 0 | 1 | 2 | 3 |
|-----|--|---|---|---|---|
| 7. | Had a change in daily routine? | 0 | 1 | 2 | 3 |
| 8. | Felt like the drug was toxic/harmful? | 0 | 1 | 2 | 3 |
| 9. | Fell asleep/slept through dose time? | 0 | 1 | 2 | 3 |
| 10. | Felt sick or ill? | 0 | 1 | 2 | 3 |
| 11. | Felt depressed/overwhelmed? | 0 | 1 | 2 | 3 |
| 12. | Had problems taking pills at specified times (with meals, on empty stomach, etc.)? | 0 | 1 | 2 | 3 |
| 13. | Ran out of pills? | 0 | 1 | 2 | 3 |
| 14. | Felt like treatment was working? | 0 | 1 | 2 | 3 |

SYNERGY ADHERENCE QUESTIONNAIRE: GROUP B

| Date | | Study ID | Study Visit | | | |
|---------------|--|---|------------------------------|--|--|--|
| • | | of GS-7977/GS-5885 (blue pill) have you missed since | - | | | |
| 2. How many | doses | of GS-9669 (white pills) have you missed since your | ast study visit? | | | |
| 3. Since your | last stu | udy visit, how often did you take your study medicati | ons with food? Check one. | | | |
| | | All of the time | | | | |
| | | Most of the time | | | | |
| | | About half of the time | | | | |
| | | Some of the time | | | | |
| | | Never | | | | |
| | | that they forget to take their pills on the weekend day ations last weekend– last Saturday or Sunday? | ys. Did you miss any of your | | | |
| | ☐ Yes | s 🗖 No | | | | |
| 5. When was | 5. When was the last time you missed any of your study medications? Check one. | | | | | |
| | | Within the past week | | | | |
| | | 1-2 weeks ago | | | | |
| | | 2-4 weeks ago | | | | |
| | | 1-3 months ago | | | | |
| | | Never skip medications or not applicable | | | | |
| | | | | | | |

6. People may miss taking their medications for various reasons. Here is a list of possible reasons why you may miss taking your medications. Have you ever missed taking your study medications because you: (Circle one response for each question.)

| | | Never | Rarely | Sometimes | Often |
|----|---|-------|--------|-----------|-------|
| 1. | Were away from home? | 0 | 1 | 2 | 3 |
| 2. | Felt hassled or inconvenienced by medicine? | 0 | 1 | 2 | 3 |
| 3. | Simply forgot? | 0 | 1 | 2 | 3 |
| 4. | Had too many pills to take? | 0 | 1 | 2 | 3 |
| 5. | Felt worse when you took pills? | 0 | 1 | 2 | 3 |

SYNERGY ADHERENCE QUESTIONNAIRE: GROUP B

| 6. | Did not want others to notice you taking medication? | 0 | 1 | 2 | 3 |
|-----|--|---|---|---|---|
| 7. | Had a change in daily routine? | 0 | 1 | 2 | 3 |
| 8. | Felt like the drug was toxic/harmful? | 0 | 1 | 2 | 3 |
| 9. | Fell asleep/slept through dose time? | 0 | 1 | 2 | 3 |
| 10. | Felt sick or ill? | 0 | 1 | 2 | 3 |
| 11. | Felt depressed/overwhelmed? | 0 | 1 | 2 | 3 |
| 12. | Had problems taking pills at specified times (with meals, on empty stomach, etc.)? | 0 | 1 | 2 | 3 |
| 13. | Ran out of pills? | 0 | 1 | 2 | 3 |
| 14. | Felt like treatment was working? | 0 | 1 | 2 | 3 |